## PSJ3 Exhibit 363

## DRAFT HDMA Key Message Points on Prescription Drug Abuse

- Prescription drug abuse is a complex and serious problem in this country that
  calls for a collaborative effort on the part of doctors, pharmacists, distributors,
  manufacturers, and state and federal authorities to comprehensively address the
  epidemic.
- Prescription drug abuse prevention efforts need to balance combatting the diversion and illegitimate use of medicines, while avoiding disruptions and shortages for legitimate patients.
- Our members work proactively with DEA, local law enforcement and others to investigate potential cases of diversion. Primary distributors exercise due diligence and have processes in place to monitor and report suspicious orders to help ensure that those who purchase controlled substances from distributors intend to dispense them only to patients who need them.
- There are numerous factors, aside from volume, that our members consider when processing an order. These include:
  - Pharmacy size;
  - Hours of operation;
  - Patient demographics;
  - Geographic proximity to urban areas; and,
  - Proximity to hospital and surgery centers, pain management clinics, nursing homes, cancer clinics and hospice providers.
- From responding to the aftermath of hurricanes to establishing mobile operations for communities ravaged by tornadoes, pharmaceutical distributors have always partnered with state and federal agencies to address critical national priorities. Our approach to prescription drug abuse is no different.
- HDMA works with stakeholders across the supply chain the National Governors
  Association (NGA), the Community Anti-Drug Coalitions of America (CADCA), the
  Partnership for Safe Medicines, the Partnership at Drugfree.org's "Medicine
  Abuse Project," and the Alliance to Prevent the Abuse of Medicines to identify
  and implement workable solutions.

## **Working with DEA**

- HDMA and our members share a common commitment with the DEA to ensure that we have a safe and efficient pharmaceutical supply chain for patients. To that end, we ask for proportionate enforcement by DEA, coupled with appropriate and clear guidance.
- GAO's recent recommendations in their report: More DEA Information about Registrants' Controlled Substances Roles Could Improve Their Understanding and Help Ensure Access reaffirm HDMA's long-standing position that enhanced communication, coordination and collaboration between the DEA and supply chain stakeholders is one of the keys to successfully mitigating prescription drug abuse and diversion.
- GAO's findings also underscore the importance of the current federal legislation, the Ensuring Patient Access and Drug Enforcement Act of 2015, which will help strengthen the relationship between supply chain stakeholders and the DEA, while encouraging productive dialogue between all parties.
- HDMA has met with the DEA seeking clarification and guidance on the agency's expectations of an anti-diversion program for wholesale distributors and we have encouraged greater information sharing between the agency and our industry.
- Without complete information, each distributor operates in a silo and is left to combat the diversion problem on its own:
  - Unaware that a new pharmacy customer may have been cut off by another distributor who had concerns about potential diversion at that pharmacy; or,
  - Unaware that an existing pharmacy customer is ordering controlled substances from multiple distributors; or,
  - Unaware that a specific pharmacy may be dispensing controlled substances for a physician who is writing prescriptions for patients when there is no legitimate medical need.
- Distributors should not be held accountable for diversion by parts of the supply chain that they do not control. On one end, distributors do not manufacture product or determine which products are approved for legitimate use. On the other end of the continuum, distributors do not prescribe or dispense products to patients, nor do they determine which prescribers or dispensers receive licenses to operate. They only distribute FDA approved medicines to federally and state licensed healthcare providers.